K130331

JUL 26 2013

510(K) SUMMARY AS REQUIRED BY SECTION 807.92(c)

1.- SUBMITTER INFORMATION:

Company Name: Sauflon Pharmaceuticals Ltd.

Address: 49 – 53 York Street
Twickenham
Middlesex
TW1 3LP

Phone: 020 8322 4200

Fax: 020 8891 2833

Contact Person: Dr Christopher Smejkal

DATE SUMMARY PREPARED: 16th January 2013

DEVICE NAME:

Trade Name: **Sauflon Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker**

Common Name: Soft Contact Lens

Classification: CLASS II (21 CFR 886.5925) CODE –LPL, MVN
SOFT (HYDROPHILIC) CONTACT LENS

2.- SUBSTANTIAL EQUIVALENCE:

The sponsor considers the **Sauflon Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker** to be substantially equivalent to the Acuvue Trueye (Narafilcon A) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear single use which has been approved pursuant to K073485, and Air Optix (Lotrafilcon B) Soft (Hydrophilic) Visibility Tinted Contact Lens for Daily Wear which has been approved pursuant to K033919/K073459.

3.- DESCRIPTION of the DEVICE:

The Sauflon Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is available as a single vision, toric and multifocal lens. The lens material (somofilcon A) is a hydrophilic co-polymer of silicone containing monomers and hydrophilic monomers which is cross-linked with tetraethyleneglycol dimethacrylate. When hydrated the lens consists of 44.0%

somofilcon A and 56.0% water by weight of saline immersed in normal saline. A benzophenone UV absorbing monomer is used to block UV radiation.

The average transmittance characteristics are less than 5% in the UVB range of 280 to 315nm and less than 30% in the UVA range of 316-380nm

The Sauflon Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Chord Diameter: 13.0mm to 15.5mm
- Centre Thickness: 0.03mm to 0.50mm
- Base Curve: 7.5mm to 9.30mm
- Powers: -20.00 DS to +20.00 DS
- Toric Cylinder options: -0.75, -1.25, -1.75 and -2.25
- Toric Axis options: 10^{o} to 180^{o} (10^{o} steps).
- Multifocal Add:

  Lens "LOW" = "low" for spectacle near ADD lens (Max +2.25 ADD)
  Lens "HIGH" = "high" for spectacle near ADD lens (+2.50 ADD or greater)

The physical/optical properties of the lenses are:

- Refractive Index: 1.4003
- %Transmittance @ 590nm: 98.13
- %Transmittance @ 280-315nm: 0.71
- %Transmittance @ 316-380nm: 20.62
- Surface Character: Hydrophilic
- Water Content: 56%
- Oxygen Permeability (DK): 60×10^{-11} (cm^2/sec) (ml O2/ml x mmHg) at 35^{o}C (Fatt Method for determination of oxygen permeability).
- Specific Gravity: 1.17

4.- INDICATIONS FOR USE

Sauflon Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for:

The **SAUFLON CLARITI 1 DAY** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **SAUFLON CLARITI 1 DAY TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or

aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The **SAUFLON CLARITI 1 DAY MULTIFOCAL** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.

The **SAUFLON CLARITI 1 DAY MULTIFOCAL TORIC** (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.

The eye care professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore no cleaning or disinfecting is required.

Sauflon Clariti 1 Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact lens with UV blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.

5.- PREDICATE DEVICES

The sponsor considers the SAUFLON CLARITI 1DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker to be substantially equivalent to the Acuvue Trueye (Narafilcon A) Soft (hydrophilic) Visibility Tinted Contact Lens for Daily Wear single use which has been approved pursuant to K073485, and Air Optix (Lotrafilcon B) Soft (hydrophilic) Visibility Tinted Contact Lens for Daily Wear which has been approved pursuant to K033919/K073459.

The following table summarises the primary features for this comparison, illustrating the similarities and differences.

SAUFLON CLARITI 1 DAY CONTACT LENS 510(k)

Comparison of Physical / Optical Properties for the SAUFLON CLARITI 1 Day (somofilcon A) Soft Hydrophilic Contact Lens with UV Blocker vs Acuvue Trueye (Narafilcon A) and Air Optix (Lotrafilcon B) Soft (hydrophilic) Visibility Tinted Contact Lenses for Daily Wear			
	PREDICATE DEVICE – ACUVUE TRUEYE (K073485)	**PREDICATE DEVICE – AIR OPTIX (K033919/K073459)**	**SUBJECT DEVICE - SAUFLON CLARITI**
LENS MATERIAL	Narafilcon A	Lotrafilcon B	Somofilcon A
INDICATIONS FOR USE	Daily wear single use	Daily wear monthly replacement	Daily wear single use
MANUFACTURING PROCESS	Cast Moulding	Cast Moulding	Cast Moulding
WATER CONTENT	47%	33%	56%
REFRACTIVE INDEX	1.41	1.42	1.40
LIGHT TRANSMITTANCE	85% minimum	≥96%	≥96%
DK @35°C (EDGE CORRECTED)	100 (polarographic method)	110 (Coulometric method)	60 (polarographic method)
POWERS	-20.00 to +20.00 D	-20.00 to +20.00 D	-20.00 to +20.00 D
COLOUR	Blue Visibility Tint	Blue Visibility Tint	No Visibility Tint

SAUFLON CLARITI 1 DAY CONTACT LENS 510(k)

TINT	CI Reactive Blue Dye 4	Copper phthalocyanine	none
UV BLOCKER	Benzotriazole	None	Benzophenone
MODULUS (MPa)	0.66	0.92	0.55
TENSILE STRENGTH (MPa)	0.72	0.9	1.05
ELONGATION AT BREAK %	170	205	163
PACKAGING MATERIALS	Injected molded polypropylene blisters covered by aluminium foil laminate and blister strips are packed into printed cartons	Injected molded polypropylene blisters covered by aluminium foil laminate and blister strips are packed into printed cartons	Injected molded polypropylene blisters covered by aluminium foil laminate and blister strips are packed into printed cartons
PACKAGING SOLUTION	Buffered saline solution containing up to 0.01% methyl ether cellulose	Phosphate buffered saline solution	Borate buffered saline solution containing 0.05% poloxamer
PACKAGING METHOD	Hermetically sealed blister pack	Hermetically sealed blister pack	Hermetically sealed blister pack

6.- PHYSICOCHEMICAL STUDIES

The physical, optical and chemical properties of the lenses as assessed by various test methods show substantial equivalency with the predicate devices as illustrated in the preceding table. Studies were also conducted to verify that leachable substances were either low or below measurable levels to assuage any concerns for its intended use.

7.- TOXICOLOGY STUDIES

Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact Lenses were assessed using ISO 10993 standards for cytotoxicity, maximization sensitisation, ocular irritation and systemic toxicity. All results passed with no evidence of adverse clinical effects caused by the lens.

8.- HUMAN CLINICAL STUDIES

A clinical study was conducted to evaluate the safety and efficacy of SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker by comparison with Air Optix Aqua hydrophilic contact lenses (Ciba Vision Inc.). Subjects used OptiFree Replenish solution (Alcon Laboratories Inc.) for daily lens maintenance, care and storage. The results of this study showed the safety, acceptability and substantial equivalence of the Sauflon CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker to the predicate device for its intended use.

9.- CONCLUSIONS

Based on the above evaluations the SAUFLON CLARITI 1 DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is substantially equivalent to the predicate, marketed lenses. Based on these evaluations the SAUFLON CLARITI 1 DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Christopher Smejkal, M.D.
Sauflon Pharmaceuticals, Ltd.
Strategic Technical Projects Manager
49 - 53 York St.
Twickenham, Middlesex
United Kingdom TW1-3LP

Re: K130331/S002
Trade Name: Sauflon Clariti 1-Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: II
Product Code: MVN, LPL
Dated: July 1, 2013
Received: July 8, 2013

Dear Dr. Smejkal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130331

Device Name: Sauflon Clarit 1-Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker

Indications For Use:

The SAUFLON CLARITI 1-DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The SAUFLON CLARITI 1-DAY TORIC (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.

The SAUFLON CLARITI 1-DAY MULTIFOCAL (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.

The SAUFLON CLARITI 1-DAY MULTIFOCAL TORIC (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV Blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.

The eye care professional should prescribe the lenses for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfecting is required. Sauflon Clariti 1-Day (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lenses with UV Blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joseph C. Hutter -S
2013.07.22 15:45:02 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K130331